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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/294,494	04/20/99	EDELSON	R 270425.003

EXAMINER	
NGUYEN, Q	
ART UNIT	**PAPER NUMBER**
1632	7

HM22/0214

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DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/294,494	EDELSON, RICHARD LESLIE	
	Examiner	Art Unit	
	Quang Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-27 and 46-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-27 and 46-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,4* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group II comprising claims 13-27 and 46-60 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the claims recited interrelated subject matter and that the examination of the claims *in toto* as originally submitted would not be unduly prolonged or burdensome. This is not found persuasive because the composition comprising functional antigen presenting cells derived from monocytes and a package preparation comprising the same can be prepared or used in a materially different process of making or using that product. For examples, the claimed composition comprising functional antigen presenting cells can be made using the processes disclosed by Tedder et al. (U.S. Patent No. 5,849,589) or Garbe et al. (Blood 92, No. 10, Supplement 1, 165a, 1998) or Akagawa et al. (Blood 88:4029-4039, 1996) to be discussed in detail below; and that the claimed composition can be used an immunogen for preparation of monoclonal antibodies directed against antigen presented by functional dendritic cells. Additionally, the methods of Group I and III require different steps and different considerations for expected end-results. For example, a step of treating disease effector agents to render them either apoptotic or inactive and an expectation of therapeutic results in the form of a vaccine are required for the method of Group III. Furthermore, a search of one embodiment does not necessarily encompass the requirements of the other embodiments.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12, 28-45 and 61-63 are withdrawn from further consideration because they are directed to non-elected inventions and they are already cancelled. It is noted that there is no such "provisionally cancellation of claims". The claims are either cancelled or not cancelled. It is further noted that Applicant requested for an interview regarding to a streamline prosecution of the present application, but due to the constraint of time limitation and it is the responsibility of Applicant to set up an interview date, an interview was not pursued prior to this Office Action.

Claims 13-27 and 46-60 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16, 20-27, 46-52 and 56-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 24, 46, 60 and their dependent claims 14-16, 20-23, 25-27, 47-52, 56-59 contain an improper Markush language. The phrase "at least one of ....., and" renders the claims indefinite. The term "and" should be replaced by - - or - - to overcome this rejection. Also in claim 13 and its dependent claims, the term "capable of" render the claims indefinite. Does the photoactivatable agent form photoadducts with cellular components or does it not? Clarification is needed.

Similarly, claims 20 and 27 contain an improper Markush language. The phrase "at least one of GM-CSF and IL-4" renders the claims indefinite. The term "and" should be replaced by - - or - - to overcome this rejection.

In claims 15, 16, 47 and 48, the terms "from about" and "to about" render the claims indefinite because the terms are not defined in the specification and it is unclear what is encompassed by the length of the recited incubating period. The metes and bounds of the claims can not be clearly determined.

The term "substantial amounts" in claims 24, 60 and dependent claims of 24 is a relative term which renders the claims indefinite. The term "substantial amounts" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how much of plasticizer being leached that one would consider to be a substantial amount. Clarification is requested.

Claim 23 is indefinite because as a method claim, it does not recite any step and it is improperly dependent on a composition claim. Clarification is needed. For the purpose of a compact prosecution, the claim is treated as a composition claim that is dependent on claim 22.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 13-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Garbe et al. (Blood 92, No. 10, Supplement 1, 165a, 1998, PTO-1449 in paper no. 4).

The claims are drawn to a composition comprising functional dendritic antigen presenting cells derived from monocytes which have been incubated following their treatment by at least one of: (1) exposure to physical perturbation, (2) irradiation in the presence of a photoactivatable agent that forms photoadducts with cellular components, or (3) treatment with a DNA binding agent; the same composition further comprising at least one of GM-CSF or IL-4 (claim 20) or the same composition wherein it further comprises at least one selected antigen for presentation by the dendritic cells (claim 21).

Garbe et al. disclose the generation of CD1a+ dendritic cells from monocytes in the presence of IL-4, GM-CSF and TGFβ under serum-free conditions within 5 days of culture (second full paragraph, lines 6-9). Garbe et al. further teach that in the presence of both TGFβ and tetanus toxoid, the generated dendritic cells were less effective to stimulate the proliferation of primed autologous T-cells as compared to dendritic cells being depleted of TGFβ before being matured in the presence of TNF-α (second paragraph, lines 12-16). It is noted that the instant claims are composition by process

claims, and the composition comprising CD1a+ dendritic cells disclosed by Garbe et al. is indistinguishable from that of the present invention. For this instance, the processes in making the same composition are not given any patentable weight. Furthermore, there is no disclosure of a feature to the claimed composition that distinguishes it from the composition of Garbe et al. Therefore, Garbe et al. clearly anticipate the instant claimed invention.

Claims 13-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Tedder et al. (U.S. Patent No. 5,849,589).

Tedder et al. disclose a composition comprising induced differentiated monocytes into dendritic cells in the presence of GM-CSF, IL-4 and TNFα (column 2, lines 19-37). Furthermore, Tedder et al. teach that the dendritic cells are plated in cultured dishes and exposed to antigen in a sufficient amount and for a sufficient period of time to allow the antigen to bind to the dendritic cells (column 11, lines 51-57).

As noted above the instant claims are composition by process claims, and there is no disclosure of a feature to the claimed composition that distinguishes it from the composition of Tedder et al. Therefore, Tedder et al. clearly anticipate the instant claimed invention.

Claims 13-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Edelson et al. (U.S. Patent No. 5,820,872, PTO-1449 in paper no. 2).

Edelson et al. disclose a preparation comprising a leukocyte preparation, including monocytes, being exposed to irradiation in the presence of a photoactivatable agent to form a photo-inactivated cell preparation which is further exposed to a plurality of tumor-derived antigens to form cellular vaccine (column 4, lines 40-48; column 5, lines 8-31; column 11, lines 22-59). In addition, Edelson et al. teach that for enhancing expression of empty major histocompatibility complex molecules, the cell preparation is further contacted with a cytokine including granulocyte monocyte conlony stimulating factor (column 9, line 66 continues to line 12 of column 10).

As noted previously the instant claims are composition by process claims, and there is no disclosure of a feature to the claimed composition that distinguishes it from the composition of Edelson et al. Therefore, Edelson et al. clearly anticipate the instant claimed invention.

Claims 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Akagawa et al. (Blood 88:4029-4039, 1996).

Akagawa et al. disclose the generation of CD1+relB+ dendritic cells in the presence of GM-CSF plus IL-4. The monocyte-derived dendritic cells can be maintained in the terminally differentiation of dendritic cells with TNFα (See abstract and page 4032, column 2, second and third full paragraphs). Since there is no disclosure of a feature to the claimed composition that distinguishes it from the composition of Akagawa et al., the reference clearly anticipates the claimed invention.

Claims 13-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al. (U.S. Patent No. 6,010,905).

Claims 13-23 are drawn to a composition comprising functional dendritic antigen presenting cells derived from monocytes which have been incubated following their treatment by at least one of: (1) exposure to physical perturbation, (2) irradiation in the presence of a photoactivatable agent that forms photoadducts with cellular components, or (3) treatment with a DNA binding agent.

Cohen et al. teach the preparation of monocytes having increasing the antigen presenting ability and with the phenotype of an activated myeloid dendritic cell by contacting the monocytes with an agent, preferably a calcium ionophore, which elevates the intracellular calcium concentration to a level sufficient and effective to increase said antigen presenting ability (column 4, lines 13-18, column 5, lines 5-12). Additionally, Cohen et al. disclose the preparation of the same composition further comprising the presence of a second agent selected from the group consisting of rhGM-CSF, rhIL-4, rhIL-12, rhIL-2, and rhTNFalpha (column 5, lines 5-12). Cohen et al. further teach contacting the monocytes isolated from the blood of a subject with a cancer with an agent which increases the intracellular calcium concentration, thereby enhancing the antigen presenting ability of the monocytes, then exposing the monocytes to tumor antigens from the cancer. The treated monocytes cells are then transferred back into the patient with the cancer for treatment purposes (column 5, lines 34-43). Cohen et al. also teach that the dendritic cells can also be challenged with antigens from the surface

of HIV-1 or other disease carrying agents such as cancer cells of the breast, brain, liver or stomach (column 38, lines 14-25).

As noted previously the instant claims are composition by process claims, and there is no disclosure of a feature to the claimed composition that distinguishes it from the composition of Cohen et al. Therefore, Cohen et al. clearly anticipate the instant claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Cohen et al. (U.S. Patent No. 6,010,905) or Garbe et al. (Blood 92, No. 10,

Supplement 1, 165a, 1998, PTO-1449 in paper no. 4) or Tedder et al. (U.S. Patent No. 5,849,589) in view of Patel (U.S. Patent No. 5,167,657).

Claims 24-27 are directed to a packaged preparation comprising: a composition comprising functional dendritic antigen presenting cells derived from monocytes which have been incubated following their treatment by at least one of: (1) exposure to physical perturbation, (2) irradiation in the presence of a photoactivatable agent that forms photoadducts with cellular components, or (3) treatment with a DNA binding agent; and a container which does not leach plasticizer and which is sufficiently porous to permit exchange of gases for storing the composition.

Cohen et al. teach the preparation of monocytes having increasing the antigen presenting ability and with the phenotype of an activated myeloid dendritic cell by contacting the monocytes with an agent, preferably a calcium ionophore, which elevates the intracellular calcium concentration to a level sufficient and effective to increase said antigen presenting ability (column 4, lines 13-18, column 5, lines 5-12). Additionally, Cohen et al. disclose the preparation of the same composition further comprising the presence of a second agent selected from the group consisting of rhGM-CSF, rhIL-4, rhIL-12, rhIL-2, and rhTNFalpha (column 5, lines 5-12). Cohen et al. further teach contacting the monocytes isolated from the blood of a subject with a cancer with an agent which increases the intracellular calcium concentration, thereby enhancing the antigen presenting ability of the monocytes, then exposing the monocytes to tumor antigens from the cancer. The treated monocytes cells are then transferred back into the patient with the cancer for treatment purposes (column 5, lines 34-43). Cohen et al.

also teach that the dendritic cells can be challenged with antigens from the surface of HIV-1 or other disease carrying agents such as cancer cells of the breast, brain, liver or stomach (column 38, lines 14-25). Garbe et al. disclose the generation of CD1a+ dendritic cells from monocytes in the presence of IL-4, GM-CSF and TGFβ under serum-free conditions within 5 days of culture (second full paragraph, lines 6-9). Garbe et al. further teach that in the presence of both TGFβ and tetanus toxoid, the generated dendritic cells were less effective to stimulate the proliferation of primed autologous T-cells as compared to dendritic cells being depleted of TGFβ before being matured in the presence of TNF-α (second paragraph, lines 12-16). Tedder et al. disclose a composition comprising induced differentiated monocytes into dendritic cells in the presence of GM-CSF, IL-4 and TNFα (column 2, lines 19-37). Furthermore, Tedder et al. teach that the dendritic cells are plated in cultured dishes and exposed to antigen in a sufficient amount and for a sufficient period of time to allow the antigen to bind to the dendritic cells (column 11, lines 51-57). The compositions disclosed by Cohen et al., Garbe et al. and Tedder et al. are indistinguishable from those of the instantly claimed invention. However, Cohen et al., Garbe et al. and Tedder et al. did not teach the packaging of the disclosed compositions in a container which does not leach the plasticizer and which is sufficient porous to permit exchange of gases for storing the composition.

Patel discloses the making and using of flexible, autoclavable, plastic containers for storing red blood cells and these containers are able to suppress hemolysis of the red blood cells (See Summary of the Invention, columns 2 and 3).

Accordingly, at the time of the instant invention it would have been obvious to the ordinary skilled artisan to package the compositions disclosed by Cohen et al., Garbe et al. and Tedder et al. in the plastic containers taught by Patel for storage and for later use of the activated dendritic cells to treat patients in need of. Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

It is further noted that the rejection of the above claims can also be applied using the teachings of Edelson et al. (U.S. Patent No. 5,820,872, PTO-1449 in paper no. 2) or Akagawa et al. (Blood 88:4029-4039, 1996) in view of Patel (U.S. Patent No. 5,167,657).

Claims 13-27 and 46-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edelson (WO 97/34472, PTO-1449 in paper no. 2) in view of any one of Tedder et al. (U.S. Patent No. 5,849,589) or Cohen et al. (U.S. Patent No. 6,010,905) or Garbe et al. (Blood 92, No. 10, Supplement 1, 165a, 1998, PTO-1449 in paper no. 4) and Patel (U.S. Patent No. 5,167,657).

Claims 13-23 are drawn to a composition comprising functional dendritic antigen presenting cells derived from monocytes which have been incubated following their treatment by at least one of: (1) exposure to physical perturbation, (2) irradiation in the presence of a photoactivatable agent that forms photoadducts with cellular components, or (3) treatment with a DNA binding agent. Claims 46-59 are directed to a composition of co-incubated populations comprising: a first population including disease effector

agents which express at least one disease associated antigen; and a second population including functional dendritic antigen presenting cells derived from monocytes which have been treated by at least one of: (1) exposure to physical perturbation, (2) irradiation in the presence of a photoactivatable agent that forms photoadducts with cellular components, or (3) treatment with a DNA binding agent; the same composition wherein the disease effector agents are selected from the group consisting of T-cell, B-cells and macrophages, and wherein the T cells include lymphoma cells, preferably cutaneous T-cell lymphoma cells; and wherein the composition further comprises at least one immunomodulatory agent. Claims 24-27 and 60 are drawn to packaged preparations comprising the above compositions in a container which does not leach plasticizer and which is sufficiently porous to permit exchange of gases for storing the composition.

Edelson teach that cultured dendritic cells can be added to or incubated with extracorporeal blood containing disease effector cells that has been treated via known photophoretic methods to increase the degree of immune responses for treating various diseases such as leukemia, lymphoma, autoimmune disease, graft versus host disease, and transplanted tissue rejection (page 4, lines 20-28 and page 5, lines 8-12). The disease effector cells include and not limit to T cells, encompassing cutaneous T cell lymphoma, B cells, and/or infected white blood cells, such as virally or bacterially infected cells (page 5, lines 8-12 and page 2, line 4-11). Edelson further teaches that the agents that are used to treat disease effector cells include photoactivatable chemical agents such as psoralens (8-MOP), porphyrin, pyrenes, phthalocyanine;

chemotherapeutic agents such as cyclophosphamide, methotrexate, cytokines including TNFalpha and interferon gamma; non-chemical agents such as UVA irradiation, X-ray irradiation, gamma-ray irradiation, and agents such as mitomycin C, cis-platinum among others (See pages 11-13 under section V). Edelson also discloses that the dendritic cells can be added or incubated with extracorporeal blood containing disease effector cells at any stage of the conventional phopheresis procedure (page 17, lines 5-11). It is also recognized that photophoresis induces the release and transfer of disease associated peptides from the treated disease effector cells to the MHC sites of the dendritic cells (page 16, lines 11-15, lines 20-23; page 22, lines 12-16). Moreover, Edelson discloses that such compositions are contained in a blood collecting bag (page 15, lines 19-28). However, Edelson does not specifically teach that functional dendritic cells in the disclosed compositions are derived from monocytes, or the time period required for the coincubation of the two cell populations to facilitate necessary direct cell to cell contact between the added dendritic cells and the treated disease effector cells or a container with recited properties.

Tedder et al. teach that monocytes can be induced to differentiate into functional dendritic cells in the presence of GM-CSF, IL-4 and TNFα in culture (column 2, lines 19-37). Furthermore, Tedder et al. teach that the dendritic cells are plated in cultured dishes and exposed to antigen in a sufficient amount and for a sufficient period of time to allow the antigen to bind to the dendritic cells (column 11, lines 51-57). Similarly, both Cohen et al. and Garbe et al. established appropriate culture conditions to induce the differentiation of monocytes, including those isolated from the blood of a patient

having a cancer, into functional dendritic cells (Cohen et al., column 4, lines 13-18, column 5, lines 5-12 and lines 34-43; Garbe et al., see abstract). Patel discloses the making and using of flexible, autoclavable, plastic containers for storing red blood cells and these containers are able to suppress hemolysis of the red blood cells (See Summary of the Invention, columns 2 and 3) and have obvious properties as those recited in the claims.

Accordingly, at the time of the instant invention it would have been obvious to the ordinary skilled artisan to utilize functional dendritic cells derived from monocytes taught by Tedder et al., Cohen et al., Garbe et al. in the compositions and methods disclosed by Edelson to arrive at the instant claimed invention. Furthermore, it would also have been obvious for one of ordinary skilled in the art to co-incubate the two cell populations in the disclosed compositions in an optimal period of time to allow the transfer of disease associated peptides from the treated disease effector cells to the MHC sites of the dendritic cells, and such compositions are contained in a blood collecting bag of the type taught by Patel. One of ordinary skilled in the art would have been motivated to carry out the above modification because as taught by Edelson such compositions would improve or enhance immune responses to treat various diseases such as leukemia, lymphoma, autoimmune disease, graft versus host disease, and transplanted tissue rejection. Moreover, Edelson does not limit the use of dendritic cells derived from any particular source in his disclosed compositions (page 14, lines 26-30). Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Conclusions

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Deborah Crouch, Ph.D., may be reached at (703) 308-1126, or SPE, Karen Hauda, at (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Papers related to this application may be submitted to Group 160 by facsimile transmission. Papers should be faxed to Group 160 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The CM1 Fax Center number is or (703) 305-3014 or (703) 308-4242.

Quang Nguyen, Ph.D.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1632